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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,738	02/16/2001	Margret Maria Sauter	2283/201	3348

7590 10/29/2003

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/785,738	Applicant(s) SAUTER ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
 4a) Of the above claim(s) 3,9-24 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-8, 25-29 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed July 31, 2003 has been entered.

Claims 1-36 are pending.

Claims 3, 9-24 and 30-32 are withdrawn from consideration.

Claims 1-2 and 33-36 are currently amended.

Claims 1-2, 4-8, 25-29 and 33-36 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-2, 4-8, 25-29, and 33-36 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed July 31, 2003 have been fully considered but they are not persuasive.

Applicant points out that claims 1 and 2 as presently amended recite that the transgenic plant has an altered ethylene response, and points to the description in the specification of 26 other DNA sequences corresponding to SH2A and SH2A-like genes in addition to the two rice sequences disclosed. Applicant also points out that the pending claims are not directed to SH2A

and SH2A-like sequences per se, and that the novelty of the invention lies in the discovery that SH2A sequences may be used to confer useful phenotypes on transgenic host cells. Applicant additionally argues that the findings of *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) are not relevant to the instant situation because the specification discloses 26 different SH2A-like gene sequences in addition to two rice sequences (reply pages 9-12).

The rejection is maintained because nucleotide sequences for SH2A or SH2A-like genes are not adequately described. With respect to plants transgenic for SH2A or SH2A-like genes having an altered ethylene response, because a specific ethylene response and its specific alteration are not recited in the claims, the limitation “having an altered ethylene response” does not describe the function of an SH2A or SH2A-like gene or its effect when expressed in a transgenic plant. With respect to the pending claims not being directed to SH2A and SH2A-like sequences per se, the Examiner maintains that such sequences must be adequately described when they are recited in the claims, even when the claims are not directed to the sequences per se, as a description of the claimed transgenic plants and cells requires a description of the transgene sequences they comprise. With respect to the description in the specification of 26 other DNA sequences corresponding to SH2A and SH2A-like genes in addition to the two rice sequences disclosed, the Examiner maintains that since the rejected claims are directed to transgenic plants comprising genes of no particular structure or function, the disclosure of 26 other DNA sequences corresponding to SH2A and SH2A-like genes as well as two rice sequences does not provide an adequate description of the claimed genus. With respect to the relevance of the findings of *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43

USPQ2d 1398, 1406 (Fed. Cir. 1997), the Examiner maintains that the findings are relevant, because the specification does not describe the correlation, if any, between the structure and function of the DNA sequences disclosed as corresponding to SH2A and SH2A-like genes.

Claims 1-2, 4, 6, 8 and 25-29, and claims dependent thereon, remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “SH2A or SH2A-like”, for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed July 31, 2003 have been fully considered but they are not persuasive.

Applicant points to pages 8-9 of the specification and points out that SH2 is likely to stand for “subtractive hybridization clone 2” since the SH2 gene was isolated by subtractive hybridization. Applicant also points to the use in public databases of the acronyms SIP (submergence induced protein) and ARD (acid-reductone dioxygenase) for SH2A or SH2A-like genes. Applicant argues that the rejection should be withdrawn because the claim language sets out and circumscribes a particular area with a reasonable degree of precision and clarity with respect to sequence homology and function when considered in light of the specification and the prior art. (reply pages 12-14).

The rejection is maintained because the acronym “SH2A” is indefinite. If SH2 does stand for “subtractive hybridization clone 2”, SH2 would likely encompass numerous genes unrelated to the gene of the claimed invention, as cloned genes are commonly assigned sequential numerical designations. Furthermore, the teachings of the specification and the prior art do not limit the acronym “SH2A” to genes of any particular structure or function.

Currently amended claims 1 and 2, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “having an altered ethylene response”. It is unclear what ethylene response is altered, as plants respond to ethylene in more than one way, such as by exhibiting increased fruit ripening, increased flower and leaf senescence, increased flower and leaf abscission, adventitious root formation, etc. It is also unclear in what way the response is altered, as a response may be altered in more than one way, such as by being increased, decreased, temporally displaced, etc. Additionally, altered is a relative term lacking a comparative basis.

Claim Rejections - 35 USC § 101 and 35 USC § 112

Claims 1-2, 4-8, 25-29, and 33-36 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed July 31, 2003 have been fully considered but they are not persuasive.

Applicant points to page 2 of the specification which discloses that SH2 genes are responsible for one of the most basic mechanisms in adaptation to hypoxic conditions, the induction of anaerobiosis-induced SH2 proteins. Applicant also points to the submergence responsive expression and ethylene regulation of SH2A and SH2B as further empirical evidence of SH2 gene function. In response to the cited reference of Doerks et al., Applicant additionally points out that the assignment of SH2 function was not made solely on the basis of amino acid

sequence homology. Applicant additionally points out that the cited reference of Doerks et al. was published 3 years prior to the filing date of the instant application, and maintains that database entries at the time of filing were likely more complete and reliable than at the time of the publication of Doerks et al. Applicant additionally points to the continuing use of amino acid sequence homology as a basis for functional assignment as evidence of its validity. In response to the assertion that the specification does not disclose a function for SEQ ID NO:1, Applicant points to the disclosure at page 2 that SH2 genes are responsible for the induction of anaerobiosis-induced SH2 proteins. Applicant additionally asserts that since the protein of the claimed invention has a clear function, the specification does teach how the claimed plants cells and constructs would be beneficial to the public. Applicant further asserts that further research would not be required to use the claimed invention as the specification provides sufficient guidance for practicing the claimed invention without undue experimentation. Applicant argues that in teaching that modulating the expression and/or activity of SH2A or SH2A-like protein in a cell allows for the growth of the cell in conditions of low oxygen, and in teaching that plants transgenic for SH2A or SH2A-like genes have an altered ethylene response, the specification teaches a specific and substantial asserted utility and satisfies the statutory requirement for the disclosure of a utility (reply pages 15-18).

The rejection is maintained because no utility has been established for a gene encoding an SH2A or SH2A-like protein and/or a plant transformed therewith. With respect to the disclosure that SH2 genes are responsible for the induction of anaerobiosis-induced SH2 proteins, such a disclosure does not support a utility for the claimed invention, as no utility for anaerobiosis-induced SH2 proteins is known or has been established. With respect to the disclosure that the

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expression of SH2A and SH2B genes are responsive to submergence and ethylene, such a disclosure does not support a utility for the claimed invention, as the correlation of gene expression with specific induction conditions does not establish a function for the gene product expressed. With respect to Applicant's assertion that the assignment of SH2 function was not made solely on the basis of amino acid sequence homology, the Examiner maintains that no specific function for SH2 has been assigned. The Examiner also maintains that the issues raised in the cited reference of Doerks et al. with respect to the assignment of protein function on the basis of amino acid homology were relevant as of the filing date of the instant application. The Examiner acknowledges the continuing use of amino acid sequence homology as a basis for the assignment of function to predicted amino acid sequences, but maintains that while a functional assignment based on sequence comparisons may categorize a protein into a particular class of proteins or provide a starting point for verifying protein activity, it does not replace empirical data for confirming protein activity, as structural homology between amino acid sequences is not always predictive of their functional homology. The Examiner also maintains that the statutory requirement for the disclosure of a utility has not been met since the utility, if any, of modulating the expression and/or activity of an SH2A or SH2A-like protein in a cell or plant has not been established. Furthermore, since the function of an SH2A or SH2A-like protein and/or its effect on a cell or plant in which it is expressed has not been established, the techniques disclosed in the specification do not provide sufficient guidance for one skilled in the art to practice the claimed invention without undue experimentation, as the function of an SH2A or SH2A-like protein and/or its effect on a cell or plant in which it is expressed would have to be determined prior to employing the disclosed techniques.

Claims 1-2, 4-8, 25-29 and 33-36 also remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed July 31, 2003 have been fully considered but they are not persuasive.

Applicant argues that since a utility for the claimed invention has been established, the rejection under 35 U.S.C. 112, first paragraph should be withdrawn (reply page 18).

The rejection under 35 U.S.C. 112, first paragraph is maintained because the rejection under 35 U.S.C. 101 is maintained.

Claim Rejections - 35 USC § 102

Claims 6-8 and 25-28 remain rejected under 35 U.S.C. 102(b) as being anticipated by Choi et al. (Mammalian Genome, 1994, Vol. 5, No. 1, pages 52-54), for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed July 31, 2003 have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn because Choi et al. teach a sequence encoding a histone somatic protein, whereas the host cells recited in claims 6-8 and the genetic construct recited in claims 25-28 are not directed to a sequence encoding a histone protein, but rather to a gene responsible for the induction of anaerobiosis-induced SH2 proteins as defined in the specification (reply page 19).

The rejection is maintained because the rejected claims do not recite any particular structure or function for an SH2A gene or an SH2A-like gene. Absent structural and functional

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limitations, the claims are anticipated by any SH2A gene or an SH2A-like gene. The rejected claims also do not require that the SH2A gene or an SH2A-like gene be responsible for the induction of anaerobiosis-induced SH2 proteins.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Claims 1-2, 4-5, 29 and 33-36 are deemed free of the prior art due to the failure of the prior art to teach or suggest a transgenic plant or plant cell comprising an isolated nucleic acid of SEQ ID NO:1, or a chimeric gene construct comprising SEQ ID NO:1.

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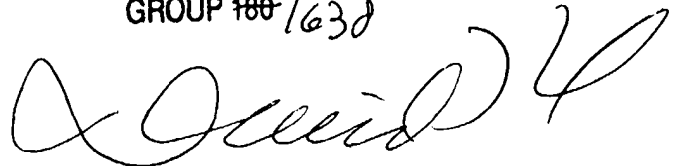
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
October 21, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180/1638

A handwritten signature in black ink, appearing to read "David T. Fox", followed by a large, stylized flourish or checkmark.